

READ THIS!

Your human subjects protocol is ready for submission to CID:

- When you have completed all required fields in the protocol template
- When you have met with Robert Riffenburgh, Ph.D., Chief of Biostatistics, NMCSd, 619-532-9414 (Wed & Fri) or 619-858-453-4334 (M, T, Thu)
- When you have included language which addresses the consent process in the "Project Description" section
- When you have obtained all required signatures
- When you submit a copy of all certificates of completion for the NIH online tutorial. Certificates are required for the P.I., all A.I.s, Medical Monitor, and all Sub-Investigators
- When you submit a copy of all CVs with the protocol. CVs are required for the P.I., all A.I.s, and the Medical Monitor
- When you submit a draft version of the consent form and patient authorization - ready for review
- When you submit an investigator's brochure and copy of the sponsor's protocol, if your study is a sponsored drug or device study
- When you submit all data collection sheets
- When you submit letters of introduction, questionnaires/surveys, notices to be posted regarding accrual, draft language for any CHCS/Outlook message intended for accrual purposes, copy of script for radio or television use regarding accrual, and copies of all videos intended for use in accruing and/or educating subjects
- When you submit a CRADA information sheet and Appendix, if your study is a sponsored drug or device study, or, if a Memorandum of Understanding is required
- When you have completed the "Budget" section, ensuring the inclusion of budget detail. If your study's annual budget exceeds \$400, you must make an appointment with Dr. Warren Lockette, Head, CID, and obtain written approval for funds requested: 619-532-8127 or welockette@nmcsd.med.navy.mil.
- When you have ensured completion of the "Department Support Statement"
- When, if you are from the Orthopaedic Department, you obtain written approval to proceed from Dr. Timothy Mologne, Research Mentor

If you have questions regarding the above requirements, please call a member of the CID Administrative staff: we're here to help:

Lynda Reed	619-532-8136	
Fran-Ellin Napoleon	619-532-8125	
Pat Angle	619-532-9416	(Animal Studies Primary Contact)
Rebecca Eveland	619-532-9927	

For CRADAs, questions may be directed to: Isabel Allard 619-532-5233